FILED
JAN 2 - 2008
OFFICE OF THE CLERK
SUPREME COURT, U.S.

NO. 06-1249

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IN THE
Supreme Court of the United States

WYETH,

Petitioner,

v.

DIANA LEVINE,

Respondent.

On Petition for a Writ of Certiorari to the
Supreme Court of Vermont

RESPONDENT'S SUPPLEMENTAL BRIEF IN RESPONSE TO BRIEF OF THE UNITED STATES

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January 2, 2008

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RESPONDENT'S SUPPLEMENTAL BRIEF IN RESPONSE TO BRIEF OF THE UNITED STATES

Seven full months after being invited to do so, the Solicitor General has provided the views of the United States on this case. The Solicitor General agrees with respondent Diana Levine that there is no division among the federal or state appellate courts on the question presented. Indeed, he acknowledges that no appellate court has ever held that a state-law claim for damages based on a drug manufacturer's failure to warn of a prescription drug hazard is preempted by the Food, Drug, and Cosmetic Act (FDCA). And he does not claim that the decision below conflicts with a decision of this Court on the same or even a similar question.

The Solicitor General also agrees with Ms. Levine that the Vermont Supreme Court found that the FDA did not consider for inclusion in Phenergan's labeling, let alone reject, the warning that Ms. Levine maintains would have prevented her life-altering injuries. And although the federal government is in a position to know exactly what the FDA did or did not consider, the Solicitor General nowhere even suggests that the Vermont Supreme Court's finding is incorrect. Finally, the Solicitor General does not argue that this case presents one of those rare cases demanding error correction. That argument would make no sense because, for seven decades, state-law tort liability of the kind affirmed by the Vermont Supreme Court has co-existed with FDA approval of prescription drugs — again, without *any* appellate authority to the contrary.

Therefore, as one would expect, because this case meets none of the Court's time-honored criteria for granting review, the Solicitor General does not recommend that the petition be granted. Nonetheless, he urges that the petition be held pending the Court's decisions in two cases — one an express preemption case involving a medical device (not a drug) and the other a case involving the preemption implications of a unique

Michigan "tort reform" statute — neither of which is likely to have any bearing on the question presented here.

The petition should be denied — and it should be denied *now*.[1]

A. The Pendency of *Riegel* and *Warner-Lambert* Provides No Basis To Hold The Petition.

The Solicitor General is wrong in maintaining that the petition should be held pending the Court's rulings in *Riegel v. Medtronic, Inc.*, No. 06-179 (argued Dec. 4, 2007), and *Warner-Lambert, LLC v. Kent*, No. 06-1498 (to be argued Feb. 25, 2008). Neither case is likely to inform the proper disposition of this case.

The issue in *Riegel* is distinct from the question here for two related reasons. First, *Riegel* presents a preemption question under the FDCA's Medical Device Amendments (MDA), not its prescription drug provisions. Medical devices are regulated differently from drugs. The MDA contains many provisions — concerning, for instance, adverse event reporting by user facilities, product recall, and subpoena power, and a savings clause, 21 U.S.C. § 360h(d) — that do not apply to drugs and may bear on the preemption question in *Riegel*.

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[1]The Solicitor General's brief focuses mainly on the merits, taking the extreme position that FDA approval of a drug generally preempts *all* state-law claims regarding the drug's safety, efficacy, or labeling. SG Br. 8. The Solicitor General's view of the merits does not bear on the question whether the petition should granted. We note only that no appellate or trial court in history has ever adopted the Solicitor General's position. *See* Opp. 13 & n.3 (explaining that no appellate court has endorsed even Wyeth's less expansive position). And we reiterate that, just last year, the FDA filed briefs that took a considerably less radical view. *See id.* at 19 n.6. Indeed, the Solicitor General acknowledged that his brief takes a position that goes beyond any position previously articulated by the FDA. SG Br. 18.

Second, *Riegel* presents *only* the question whether the MDA's *express* preemption clause, 21 U.S.C. § 360k(a), preempts certain state-law claims. *See* Pet. for Cert. in *Riegel*, No. 06-79, at i ("Whether the express preemption provision of the Medical Device Amendments to the Food, Drug, and Cosmetic Act, 21 U.S.C. § 360k(a), preempts state-law claims seeking damages for injuries caused by medical devices that received premarket approval from the Food and Drug Administration."). This case, on the other hand, involves only *implied* preemption, as the FDCA contains no express preemption provision with respect to prescription drugs. Over a decade ago, the Court decided *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996), which set forth the parameters of express preemption of state-law tort claims under the MDA. Since then, not a single appellate decision has suggested, let alone held, that the analysis in *Lohr* bears on the question whether the FDCA preempts state-law claims involving prescription drugs.

As in *Lohr*, the Court's focus in *Riegel* will be on the text of the MDA's express preemption clause and the FDA's regulations promulgated under that clause, and *not* on the implied preemption question here: whether the FDCA as a whole evinces an unspoken intent to preempt Ms. Levine's claims on the ground that those claims somehow conflict with the objectives of federal prescription drug regulation. The Solicitor General (at 21) asserts that, in *Lohr*, "this Court ... determined that implied preemption principles are relevant to the interpretation" of the MDA's preemption clause provision, but the portion of *Lohr* he cites for that proposition proves *our* point: It contains an almost word-by-word textual analysis of the MDA's preemption clause, 21 U.S.C. § 360k(a), and the FDA regulation promulgated thereunder, 21 C.F.R. § 808.1(d), *see Lohr*, 518 U.S. at 500 — an analysis that is irrelevant to the

question whether the FDCA impliedly preempts a state-law claim involving a prescription drug.[2]

Similarly, the Solicitor General is wrong that the Court's decision in *Warner-Lambert* will prove relevant here. *Warner-Lambert* involves a Michigan statute that precludes, *as a matter of state law*, any tort claim arising from a defective or inadequately labeled prescription drug if that drug was approved for marketing by the FDA and its labeling complied with that approval at the time it was marketed. Mich. Comp. Laws § 600.2946(5). The Michigan law contains a narrow exception to this state-law defense if the manufacturer intentionally withheld information from the FDA, or misrepresented information to the FDA, that was required to be submitted to the agency, *and* the agency would not have approved the drug or would have withdrawn the drug's approval if the proper information had been submitted. *Id.* § 600.2946(5)(a). The question presented in *Warner-Lambert* is only whether a Michigan tort plaintiff's attempt to make the showings necessary to avoid the defense provided by the Michigan statute is preempted by federal law.

The narrow issue in *Warner-Lambert* has nothing to do with this case. The issue here — whether a traditional common-law damages claim premised on a drug's inadequate labeling is preempted by the FDCA — is exactly the issue taken off the table *as a matter of state law* by the Michigan statute, which

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[2]This Court's decisions have demonstrated that claims of express and implied preemption demand analytically distinct analyses. *See, e.g., Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 458-59 (2005) (Thomas, J., concurring) (making this point and noting "this Court's increasing reluctance to expand federal statutes beyond their terms through doctrines of implied pre-emption"); *Sprietsma v. Mercury Marine*, 537 U.S. 51 (2002) (conducting entirely separate implied and express preemption analyses); *Lohr*, 518 U.S. at 503.

generally provides a defense to such a claim. Therefore, that issue, by definition, cannot be presented in *Warner-Lambert*. And put the other way around, the issue that *is* presented in *Warner Lambert* has no bearing on this case because Ms. Levine was not was required by state law to make the showings demanded by the exception to Michigan's unique statute. Her claim rested entirely on Wyeth's failure to adequately instruct doctors and patients about administration of Phenergan. It did not depend on whether the FDCA required particular information to be submitted to the FDA, whether Wyeth failed to provide that information to the FDA, or what the FDA would or would not have done had it received that information.

In sum, neither *Riegel* nor *Warner-Lambert* provides any reason for holding the petition.

B. The Solicitor General's Brief Underscores Wyeth's Attempt To Seek Review On A Question Not Genuinely Presented By This Case.

The question presented by Wyeth is whether the "labeling judgments" made by the FDA regarding a drug's safety and efficacy preempt state-law product liability claims premised on "differing label judgments." Pet. i. Our opposition explains (at 14-21) that this case does not genuinely present that question because the Vermont Supreme Court correctly found, as a matter of fact, that Ms. Levine's recovery was *not* based on a labeling judgment different from a labeling judgment made by the FDA. Wyeth's claim for preemption rests on its assertion that the FDA had specifically considered and rejected a label change that would have prohibited IV-push administration of Phenergan. But the Vermont Supreme Court rejected that argument as having *no factual basis in the record*, *see* Pet. App. 17a-19a, and the Solicitor General takes no issue with that finding. Thus, before the Court could resolve the question presented, Wyeth would have to convince it to take two highly

unusual steps: first, to grant review "when the asserted error consists of erroneous factual findings," S. Ct. Rule 10, and, then, to overturn the Vermont Supreme Court's factual findings.

The Solicitor General recognizes that, in its present posture, this case does not present the question that *Wyeth* has posed. He acknowledges that the Vermont Supreme Court's holding is based on that court's "findings of fact," and that for Wyeth to prevail on *its* question presented it must "dispute the Vermont Supreme Court's interpretation of the record in this case." SG Br. 20. In other words, the Solicitor General realizes that the question as stated by Wyeth is not cert-worthy. So, undeterred by the disconnect between the Vermont Supreme Court's findings and Wyeth's question presented, the Solicitor General has changed the question presented to make the Vermont's factual findings irrelevant. *See id.* at (I). He says that it makes no difference whether the FDA even considered, let alone rejected, a label warning that would have precluded IV-push administration. *Id.* at 20. As long as the FDA had before it information regarding the "relevant risk" — and, according to the Solicitor General, that means here only the highly general risk of arterial exposure to Phenergan injection, *id.* at 14 — FDA approval of a drug "preempts state law claims challenging the drug's safety, efficacy, or labeling." *Id.* at 8. Putting aside the Solicitor General's unprecedented view of preemption, *see supra* note 1, his attempt to alter the question presented is improper and serves only to underscore that the *actual* question presented is not before the Court unless it first overturns the Vermont Supreme Court's factual findings.[3]

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[3]The Solicitor General must know that those factual findings will not be overturned by this Court. The FDA — whose General Counsel appears on the Solicitor General's brief — knows what it did with respect to the Phenergan label, and the Solicitor General's brief does not contest the

(continued...)

For its part, even Wyeth does not embrace the Solicitor General's all-encompassing view of preemption. To the contrary, its appellate counsel (who remains counsel of record in this Court) stated at oral argument in the Vermont Supreme Court that

> I want to emphasize to the Court that the issue as presented here is very narrow and very particularized. . . . It's focused on Phenergan in the facts of this case. Wyeth is not contending for field preemption, for the ouster of Vermont law, tort law [is] not at issue here . . . nor are we arguing that the mere compliance with federal labeling requirements in and of itself creates a conflict preemption.

Vt. S. Ct. Oral Arg. Tr. 7 (Oct. 5, 2005). The Solicitor General's view of preemption is anything but "narrow and particularized." In his view, "mere compliance with federal labeling requirements" *does* "in and of itself create . . . conflict preemption." *See* SG Br. 8. Not only does Wyeth not present that question in its petition, but its counsel affirmatively waived any broader argument in the court below.

In sum, the case presents neither the question as framed by Wyeth nor the broader question that the Solicitor General would prefer. For these reasons, review should be denied.

C. Recent FDCA Amendments Provide Another Reason To Deny Review.

An amendment to the FDCA enacted after the petition and opposition were filed provides another reason to deny review.

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[3](...continued)
Vermont Supreme Court's finding that "[t]here is no evidence that the FDA intended to prohibit defendant from strengthening the Phenergan label" with an instruction precluding IV push. Pet. App. 19a.

On September 27, 2007, Congress passed the Food and Drug Administration Amendments Act of 2007 (FDAAA), Pub. L. No. 110-85, 121 Stat. 823. Section 901(a) of FDAAA bolsters the FDA's authority to require a manufacturer to change a drug label if the agency becomes aware of information that it believes should be included in the label. 121 Stat. at 924 (to be codified at 21 U.S.C. § 355(o)(4)). This provision does not alter drug companies' longstanding statutory and regulatory obligations to revise inadequate labels and to seek agency approval of label changes even in the absence of an agency demand. Nonetheless, in an apparent effort to ward off any future claim of preemption, section 901(a) includes a "rule of construction":

> This paragraph shall not be construed to affect the responsibility of the responsible person or the holder of the approved application under section 505(j) to maintain its label in accordance with existing requirements, including subpart B of Part 201 and sections 314.70 and 601.12 of Title 21, Code of Federal Regulations (or any successor regulations).

121 Stat. at 925-26 (to be codified at 21 U.S.C. § 355(o)(4)(I)). By establishing that the FDA's new authority to order label changes does not alter manufacturers' existing obligations to assure that labels promote patient safety, the rule of construction underscores the importance of 21 C.F.R. § 314.70(c)(6), which allows manufacturers to amend labels to strengthen warnings and instructions and to add contraindications without FDA pre-approval, and 21 C.F.R. § 201.80(e), which provides that drug "labeling shall be revised to include a warning as soon as there is reasonable evidence of an association of a serious hazard with a drug."

Section 901(a)'s legislative history indicates that the "rule of construction" was motivated by a desire to assure that the

FDA's new authority to demand label changes would not preempt future damages claims. *See* 153 Cong. Rec. S11832, col. 3 - S11833, cols. 1-2 (Sept. 20, 2007) (Sen. Kennedy); *id.* at S11834, cols. 2-3 (Sen. Leahy); *id.* at S11835, col. 3 (Sen. Durbin). Indeed, even a senator who would have preferred statutory language that would have "occupied the field" of drug labeling and preempted damages suits construed the rule of construction as having anti-preemptive effect, thereby "open[ing] the floodgates" for suits and affording "a definite boon for trial lawyers." *Id.* at S11836, col. 3 - S11837, col. 1 (Sen. Allard).

As noted, we believe that the rule of construction underscores Congress's view that, in the future, state-law damages liability should continue to co-exist with the FDA's enhanced power to demand label changes. But that question will be fiercely debated in case after case. Indeed, the issue has already been briefed in one multi-district case, *In re Seroquel Products Liability Litigation*, MDL 1769 (M.D. Fla.). *See also* Arnold & Porter LLP, Client Advisory — The FDA Amendments Act of 2007, at 9, available at http://www.arnoldandporter.com/resources/documents/A&PCA_ExecutiveSummary-TheFDA_Oct107_V2.pdf (noting that the rule of construction is "undoubtedly a tool that will be used by plaintiffs seeking to undermine preemption in 'failure to warn' cases").

The meaning of the rule of construction is not, of course, at issue in *Riegel* or *Warner-Lambert*. Nor is it at issue in Ms. Levine's case, which unfolded years before the FDAAA was enacted. But it *will be* at issue in future cases presenting the question whether the FDCA preempts state-law failure-to-warn claims regarding prescription drugs. And if the Court wishes to address that issue, despite the absence of a conflict among the lower courts, it should await input from those courts on the

meaning of the FDAAA and a case, unlike Ms. Levine's, in which the FDAAA actually applies.

CONCLUSION

In most cases, the facts of the litigants' personal circumstances are properly disregarded in deciding whether to grant review. But here — where petitioner Wyeth's claim for review is fundamentally a challenge to the lower courts' factual findings and the Solicitor General's claim for further delay is based on an unabashed effort to rewrite the question presented — Ms. Levine's circumstances should not be ignored. Diana Levine lost her arm and her livelihood nearly eight years ago. In 2004, she won a verdict compensating her for undisputed future medical expenses and lost income. Wyeth filed its petition in March 2007 and the Court called for the Solicitor General's views the next month. The Solicitor General did not respond for seven months. When he did, he *agreed* that the case was not worthy of review, but nevertheless requested further delay — based solely on speculation that pending cases presenting different questions might somehow affect the proper resolution of this case. All the while, unable to collect her judgment, Ms. Levine faces massive and ever-mounting medical debt.

Under these circumstances, enough is enough. As we said at the outset, the petition should be denied — and it should be denied *now*.

Respectfully submitted,

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